DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1999

99 APR 30 P1:46

Joan Flynn
Director, Risk Management
The Miriam Hospital
164 Summit Avenue
Providence, Rhode Island 02906

Re: Docket No. 99P-0152

Dear Ms. Flynn:

This responds to your citizen petition, dated January 25, 1999, in which the Miriam Hospital requests a temporary variance from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables, as it applies to your Pace Aide telephone electrocardiograph (ECG) transmitters. These devices are issued to your pacemaker patients for remote ECG monitoring from their home, via telephone. It is our understanding that your institution has 56 Pace Aide 10 or Pace Aide 20 devices, and 45 Pace Aide Elite or Pace Aide Timers, all of which cannot use electrode lead wires that comply with the performance standard. These devices are manufactured by TZ Medical, Inc., and the firm does not provide any adapters that would convert the devices for use with compliant electrode lead wires.

Telephone electrocardiograph transmitters are included among ten specified devices for which their electrode lead wires and patient cables are required to comply with the performance standard after May 11, 1998. On August 3, 1998, the Food and Drug Administration (FDA) issued a letter to all user facilities, notifying them of their responsibility for compliance with the performance standard. That letter extended the compliance time frame until January 1, 1999, for electrode lead wires and patient cables used with those ten specified devices. Your petition asks FDA for a further extension until December 31, 1999, by which time the subject Pace Aide devices will be replaced by devices with electrode lead wires that comply with the performance standard. You noted that this time extension is needed to schedule all patients, some of whom are out of state, to receive their replacement devices.

I am granting your variance request to extend the date of compliance for remote ECG devices currently used by your facility to December 31, 1999. However, you must discontinue use of non-compliant lead wires by that date. This means that you need to replace the ECG devices with ones that accept lead wires that comply with the performance standard by December 31, 1999.

I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

Linda D. Kahan for

Elizabeth D. Jacobson, Ph.D.
Acting Director
Center for Devices and Radiological Health

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